

Applicants respectfully request that the Examiner reconsider the restriction requirement between Group III (claims 6-18 and 20) and Group IV (claim 19). The Office action states that these two inventions are distinct as they are drawn to independent and distinct methods which differ in the method objectives, method steps, the reagents used, and have different final outcomes (see the Office action, dated December 15, 2000, on page 3, point 4, second paragraph). Applicants respectfully disagree with this assertion.

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The objective of claims 6-18 and 20 is to identify a non-binding FK506 analog that stimulates nerve growth. The method steps (as recited in claim 6, from which dependent claims 7-18 and 20 ultimately depend) are (1) screening a plurality of FK506 analogs for binding to FKBP-12, (2) selecting a FK506 analog that does not bind FKBP-12, and (3) assaying the FK506 analog that does not bind FKBP-12 for activity in promoting nerve cell growth. The reagents in the method are defined by these steps. The outcome of these claims (claims 6-18 and 20) is the identification of a non-binding FK506 analog that stimulates nerve cell growth.

Claim 19 depends from claim 18, which depends from claim 14, which depends from claim 6. Thus, all of the limitations present in claims 14 and 6 are also included in claim 19. Thus, as recited in claims 6, the objective of claim 19 is to identify a non-binding FK506 analog that stimulates nerve growth. The method steps are (1) screening a plurality of FK506 analogs for binding to FKBP-12, (2) selecting a FK506 analog that does not bind FKBP-12, and (3) assaying the FK506 analog that does not bind FKBP-12 for activity in promoting nerve cell growth. A proviso is provided (as recited in claim 14, also included in Group III) that the non-binding FK-506 analog binds FKBP-12 with a  $K_d$  of at least 10  $\mu$ M. As described above, the reagents used are defined by the steps of the claimed method. The outcome of claim 19 is the identification of a non-binding FK506 analog that stimulates nerve cell growth. The only further limitation recited in claim 19 is that "selecting more or more FK506 analogs comprises selecting one or more analogs that do not substantially inhibit FKBP-12 rotamase activity when administered to a patient at dosage levels up to about 100 mg/kg body weight/day." However, *this is not an additional method step, rather is an inherent pharmacological characteristic of the selected FK-506 analog.* Thus Applicant submits that the method objectives, method steps, the reagents used, and final outcome recited in claim 19 is the same as that of claims 6-18 and

20. The only additional limitation recited in claim 19 is a further pharmacological characteristic of the selected FK-506 analog. Thus, Applicant respectfully requests that the Examiner reconsider to restriction requirement, and include claim 19 in Group III, along with claims 6-18 and 20.

In the unlikely event that the restriction requirement is maintained, Applicant provisionally elects herein the prosecution of Group III (claims 6-18 and 20), with traverse.

### CONCLUSION

Applicants submit that the pending claims are in condition for allowance. If any matters remain to be resolved before a Notice of Allowance is issued, the Examiner is invited to telephone the undersigned patent attorney at the telephone number listed below.

Respectfully submitted,

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